

MAY 18 2009

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR§807.92(a).

807.92(a)(1)

Submitter Information

Allison Scott
The Anson Group
11460 N Meridian St., Ste 150
Carmel, Indiana 46032
Phone: (317) 569-9500 x106
Facsimile: (317) 569-9520
Ascott@ansongroup.com

Contact Person: Allison Scott

Date: March 5, 2009

807.92(a)(2)

Trade Name: 7340 & 6150 Systems

Common Name: Ultrasound Imaging System

Classification Name(s): Ultrasonic pulse Doppler imaging system 892.1550
Ultrasonic pulsed echo imaging system 892.1560

Classification Number: 90IYN; 90IYO

807.92(a)(3)

Predicate Device(s)

K051308, K052805, K060827, and K081386	6150	Esaote, S.p.A.
K081794	7340	Esaote, S.p.A.
K072786	S2000	Siemens
K061682	Voluson E8	General Electric

510(k) Summary
7340 & 6150 Systems
Esaote, S.p.A.

807.92 (a)(4)

Device Description

The 7340 and 6150 system designs remain the same as those previously cleared by FDA via K081794, K051308, K052805, K060827, and K081386, respectively, except for those features being added via this submission.

The 6150 is a mainframe ultrasound system, and the 7340 is a portable ultrasound system, both are used to perform diagnostic general ultrasound studies. Their primary modes of operation are: B-Mode, M-Mode, XView, Multi View (MView), Trapezoidal View (TPView), Doppler, Color Flow Mapping, Amplitude Doppler (AD), Tissue Velocity Mapping (TVM) and Tissue Enhancement Imaging (TEI). The systems are equipped with a LCD Color Display and are capable of operating Linear, Convex, and Phased array probes.

The 7340 and 6150 systems are manufactured under an ISO 9001:2000 and ISO 13485 certified quality system.

807.92(a)(5)

Intended Use(s)

Esaote's Model 7340 is a compact ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative (Abdominal), Laparoscopic and Other: Urologic. The 7340 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

Esaote's Model 6150 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative (Abdominal), Laparoscopic and Other: Urologic. The 6150 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

510(k) Summary
7340 & 6150 Systems
Esaote, S.p.A.

807.92(a)(6)

Technological Characteristics

The 7340 model has been cleared via K081794; the 6150 has been cleared via K051308, K052805, K060827 and K081386.

The Elastography (ElaXto) analysis is substantially equivalent to Siemens eSie Elasticity Imaging module available with S2000 system cleared via K072786.

The 3D/4D modality in Transvaginal, Transrectal and Urology applications is substantially equivalent to 3D/4D modality in the same applications available with RIC5-9-D probe of General Electric Voluson E8 system cleared via K061682.

- Clinical uses for which the 7340 and 6150 are designed, to be added with this submission, are equivalent to those of the Siemens S2000 ultrasound system, cleared via K072786 and by the General Electric Voluson E8 cleared via K061682.
- The 7340, 6150 and Siemens S2000 ultrasound systems are able to provide Elastographic analysis on real-time images, by applying low compression and retraction movements on the patient using the probe to evaluate the modification of the echo signal.
- The 7340, 6150 and General Electric Voluson E8 systems are able to provide the 3D/4D modality in Transvaginal, Transrectal and Urology applications by simultaneously controlling two independent scan planes for volumetric acquisition.
- 7340, 6150, Siemens S2000 and General Electric Voluson E8 are designed to meet the IEC60601-1 and IEC60601-2-37 safety requirements.
- 7340, 6150, Siemens S2000 and General Electric Voluson E8 provide an Acoustic Output Display feature per AIUM / NEMA standards, with equivalent Ispta and MI maximal values.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 18 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Esaote, S.p.A.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K091009

Trade/Device Name: 7340 Ultrasound Systems and 6150 Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: May 4, 2009
Received: May 5, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the 7340 Ultrasound Systems and 6150 Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

Model 7340

PA230
PA240
PA121

PA122
PA023
LA332

LA424
LA435
LA522

<u>LA523</u>	<u>CA621</u>	<u>TEE022</u>
<u>LA532</u>	<u>CA631</u>	<u>TEE122</u>
<u>C5-2</u>	<u>2 CW</u>	<u>IOE323</u>
<u>CA123</u>	<u>5 CW</u>	<u>LP323</u>
<u>CA421</u>	<u>E8-5</u>	<u>BC431</u>
<u>CA1421</u>	<u>EC123</u>	<u>BE1123</u>
<u>CA430</u>	<u>EC1123</u>	
<u>CA431</u>	<u>TRT33</u>	

Model 6150

<u>PA230</u>	<u>LA923</u>	<u>EC1123</u>
<u>PA240</u>	<u>C5-2</u>	<u>TEE022</u>
<u>PA121</u>	<u>CA123</u>	<u>TEE132</u>
<u>PA122</u>	<u>CA421</u>	<u>IOE323</u>
<u>PA023</u>	<u>CA621</u>	<u>LP323</u>
<u>LA332</u>	<u>CA430</u>	<u>BC431</u>
<u>LA522</u>	<u>CA431</u>	<u>BL433</u>
<u>LA523</u>	<u>CA631</u>	<u>BE1123</u>
<u>LA532</u>	<u>2CW</u>	
<u>LA424</u>	<u>5CW</u>	
<u>LA435</u>	<u>EC123</u>	<u>TRT33</u>

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

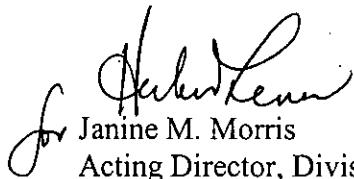
This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small

Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

Sincerely yours,



Janine M. Morris

Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Models 7340 and 6150

Indications for Use

510(k) Number (if known):

K091009

Device Name:

7340 Ultrasound Systems
6150 Ultrasound Systems

Esaote's Model 7340 is a compact ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative (Abdominal), Laparoscopic and Other: Urologic. The 7340 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

Esaote's Model 6150 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative (Abdominal), Laparoscopic and Other: Urologic. The 6150 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

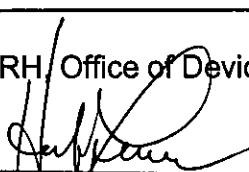
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH/Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K091009

Mod.7340

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P		P		P: 5, 6, 7, 8, 9, 10
Abdominal	P	P	P	P	P	P	P		P	E	P: 4, 5, 6, 7, 8, 9, 13
Intraoperative (Abdominal)	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9, 13
Intraoperative Neurological											
Pediatric	P	P	P	P	P	P	P		P		P: 4, 5, 6, 8, 9, 13
Small Organ [1]	P	P	P		P	P	P		P	E	P: 4, 5, 6, 8, 9, 13; N: 14
Neonatal Cephalic	P	P	P	P	P	P	P		P		P: 5, 6, 8, 9
Adult Cephalic	P	P	P	P	P	P	P		P		P: 6, 8, 9
Cardiac [2]	P	P	P	P	P	P	P	P	P	E	P: 4, 6, 7, 8, 9, 11, 12
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P		P: 4, 6, 9, 11, 12
Transesophageal (Non Cardiac)											
Transrectal	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9, 13; N: 14
Transvaginal	P	P	P		P	P	P		P		P: 5, 6, 8, 9
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P	P	P	P	P		P	E	P: 4, 5, 6, 7, 8, 9, 10, 12, 13
Laparoscopic	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9, 13
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9, 13; N: 14
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9, 13; N: 14
Other (Urological)	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9, 13

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E
(Previously cleared: k081794)

[1]

Small Organs includes Breast, Thyroid and Testicles

[2]

Cardiac is Adult and Pediatric

[3]

Combined modes are: B + M + PWD + CWD + CFM + PD

[4]

CMM

[5]

MView

[6]

3D

[7]

4D

[8]

VPan

[9]

XView

[10]

QIMT

[11]

Stress

[12]

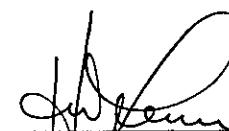
Strain

[13]

TP View

[14]

ElaXto


(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K091069

For Prescription Use Only

7340 - PA230

Intended use:

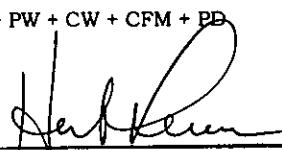
Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal	P	P	P	P	P	P	P		P	E	P: 6, 8, 9
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P		P		P: 6, 8, 9
Cardiac [2]	P	P	P	P	P	P	P	P	P	E	P: 4, 6, 8, 9, 11, 12
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)											
Musculo-skeletal Superficial (including Nerve Blocking)											
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared: k081794)

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CW + CFM + PD
- [4] CMM
- [6] 3D
- [8] VPan
- [9] XView
- [11] Stress
- [12] Strain


(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number 15091009

7340 - PA240

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PW D	CW D	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal	E	E	E	E	E	E	E		E		P: 8, 9
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic	E	E	E	E	E	E	E		E		P: 8, 9
Cardiac [2]	E	E	E	E	E	E	E	E	E		P: 4, 8, 9, 11, 12
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)											
Musculo-skeletal Superficial (including Nerve Blocking)											
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: B + M + PW + CW + CFM + PD

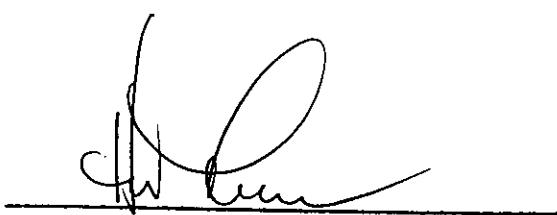
[4] CMM

[8] VPan

[9] XView

[11] Stress

[12] Strain



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K091009

For Prescription Use Only

7340 - PA121

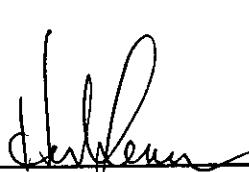
Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal	E	E	E	E	E	E	E		E		P: 8, 9
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]	E	E	E	E	E	E	E		E		P: 4, 8, 9, 11, 12
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)											
Musculo-skeletal Superficial (including Nerve Blocking)											
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CW + CFM + PD
- [4] CMM
- [8] VPan
- [9] XView
- [11] Stress
- [12] Strain


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K091009

For Prescription Use Only

7340 - PA122

Intended use:

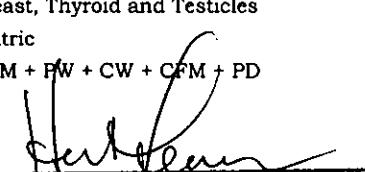
Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P	P	P	P	P		P		P: 6, 8, 9
Small Organ [1]											
Neonatal Cephalic	P	P	P	P	P	P	P		P		P: 6, 8, 9
Adult Cephalic											
Cardiac [2]	P	P	P	P	P	P	P	P	P		P: 4, 6, 8, 9, 11, 12
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P	P	P	P	P		P		P: 6, 8, 9, 12
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)											
Musculo-skeletal Superficial (including Nerve Blocking)											
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared: k081794)

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CW + CFM + PD
- [4] CMM
- [6] 3D
- [8] VPan
- [9] XView
- [11] Stress
- [12] Strain


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K091009

For Prescription Use Only

7340 - PA023

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	E	E	E	E	E	E	E				P: 8, 9
Small Organ [1]											
Neonatal Cephalic	E	E	E	E	E	E	E				P: 8, 9
Adult Cephalic											
Cardiac [2]	E	E	E	E	E	E	E				P: 4, 8, 9, 11, 12
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	E	E	E	E	E	E	E				P: 8, 9
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)											
Musculo-skeletal Superficial (including Nerve Blocking)											
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CW + CFM + PD
- [4] CMM
- [8] VPan
- [9] XView
- [11] Stress
- [12] Strain


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K091009

For Prescription Use Only

7340 - LA332

Intended use:

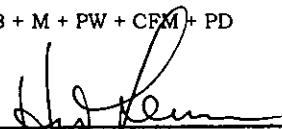
Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P	P		P: 4, 5, 6, 8, 9, 13	
Small Organ [1]	P	P	P		P	P	P	P		P: 4, 5, 6, 8, 9, 13; N:14	
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P	P		P: 4, 5, 6, 8, 9, 10, 12, 13	
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P	P		P: 4, 5, 6, 8, 9, 13; N: 14	
Musculo-skeletal Superficial . (including Nerve Blocking)	P	P	P		P	P	P	P		P: 4, 5, 6, 8, 9, 13; N: 14	
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared: k081794)

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CEM + PD
- [4] CMM
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [10] QIMT
- [12] Strain
- [13] TP View
- [14] ElaXto


Division Sign-Off
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K091009

For Prescription Use Only

7340 - LA424

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	E	E	E		E	E	E				P: 4, 5, 6, 8, 9, 13
Small Organ [1]	E	E	E		E	E	E				P: 4, 5, 6, 8, 9, 13
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	E	E	E		E	E	E				P: 4, 5, 6, 8, 9, 12, 13
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)	E	E	E		E	E	E				P: 4, 5, 6, 8, 9, 13
Musculo-skeletal Superficial (including Nerve Blocking)	E	E	E		E	E	E				P: 4, 5, 6, 8, 9, 13
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [4] CMM
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [12] Strain
- [13] TP View


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K091009

For Prescription Use Only

7340 - LA435

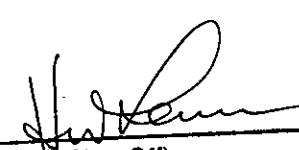
Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	E	E	E		E	E	E				P: 4, 5, 6, 8, 9, 13
Small Organ [1]	E	E	E		E	E	E				P: 4, 5, 6, 8, 9, 13; N: 14
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	E	E	E		E	E	E				P: 4, 5, 6, 8, 9, 12, 13
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)	E	E	E		E	E	E				P: 4, 5, 6, 8, 9, 13; N: 14
Musculo-skeletal Superficial (including Nerve Blocking)	E	E	E		E	E	E				P: 4, 5, 6, 8, 9, 13; N: 14
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [4] CMM
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [12] Strain
- [13] TP View
- [14] ElaXto


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K091009

For Prescription Use Only

7340 - LA522

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhacement Imaging (TEI)	CnTi	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	E	E	E		E	E	E		E		P: 4, 5, 6, 8, 9, 13
Small Organ [1]	E	E	E		E	E	E		E		P: 4, 5, 6, 8, 9, 13; N: 14
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	E	E	E		E	E	E		E		P: 4, 5, 6, 8, 9, 10, 12, 13
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)											
Musculo-skeletal Superficial (including Nerve Blocking)											
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [4] CMM
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [10] QIMT
- [12] Strain
- [13] TP View
- [14] ElaXto


(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

K091009

For Prescription Use Only

7340 - LA523

Intended use:

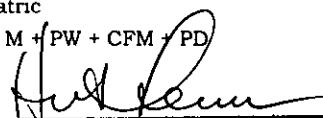
Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9, 13
Small Organ [1]	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9, 13; N: 14
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9, 10, 12, 13
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9, 13; N: 14
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9, 13; N: 14
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared: k081794)

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [4] CMM
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [10] QIMT
- [13] TP View
- [14] ElaXto



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K091009

7340 - LA532

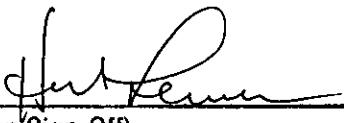
Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>											
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)	
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Abdominal)												
Intraoperative Neurological												
Pediatric	E	E	E		E	E	E		E		P: 4, 5, 6, 8, 9, 13	
Small Organ [1]	E	E	E		E	E	E		E	E	P: 4, 5, 6, 8, 9, 13	
Neonatal Cephalic												
Adult Cephalic												
Cardiac [2]												
Transesophageal (Cardiac)												
Transesophageal (Non Cardiac)												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular	E	E	E		E	E	E		E	E	P: 4, 5, 6, 8, 9, 12, 13	
Laparoscopic												
Musculo-skeletal Conventional (including Nerve Blocking)												
Musculo-skeletal Superficial (including Nerve Blocking)												
Other (Urological)												

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [4] CMM
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [12] Strain
- [13] TP View


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K091009

For Prescription Use Only

7340 - C5-2

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P		P		P: 5, 6, 8, 9, 10
Abdominal	P	P	P		P	P	P		P		P: 5, 6, 8, 9
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P		P: 5, 6, 8, 9
Small Organ [1]											
Neonatal Cephalic	P	P	P		P	P	P		P		P: 5, 6, 8, 9
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P		P: 5, 6, 8, 9, 12
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)											
Musculo-skeletal Superficial (including Nerve Blocking)											
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared: k081794)

[1]

Small Organs includes Breast, Thyroid and Testicles

[2]

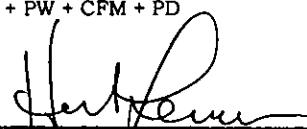
Cardiac is Adult and Pediatric

[3]

Combined modes are: B + M + PW + CFM + PD

[5]

MView



[6]

3D

[8]

VPan

[9]

XView

(Division Sign-Off)

[10]

QIMT

Division of Reproductive, Abdominal and
Radiological Devices

[12]

Strain

510(k) Number K091009

For Prescription Use Only

7340 - CA123

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P		P: 5, 6, 8, 9
Small Organ [1]	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9
Neonatal Cephalic	P	P	P		P	P	P		P		P: 5, 6, 8, 9
Adult Cephalic											
Cardiac [2]	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9, 11
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P		P: 5, 6, 8, 9, 12
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared: k081794)

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: B + M + PW + CFM + PD

[4] CMM

[5] MView

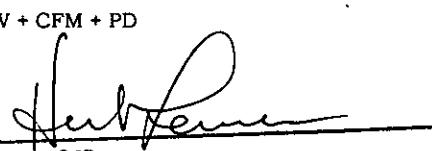
[6] 3D

[8] VPan

[9] XView

[11] Stress

[12] Strain


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K091009

For Prescription Use Only

7340 - CA421

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	E	E	E		E	E	E		E		P: 5, 6, 8, 9
Abdominal	E	E	E		E	E	E		E		P: 5, 6, 8, 9
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	E	E	E		E	E	E		E		P: 5, 6, 8, 9
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	E	E	E		E	E	E		E		P: 5, 6, 8, 9
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)											
Musculo-skeletal Superficial (including Nerve Blocking)											
Other (Urological)	E	E	E		E	E	E		E		P: 5, 6, 8, 9

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW +CFM + PD
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView


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Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number 14091009

For Prescription Use Only

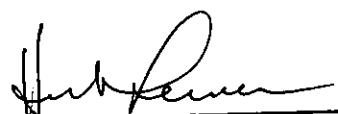
7340 - CA1421

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	E	E	E		E	E	E		E		P: 6, 8, 9
Abdominal	E	E	E		E	E	E		E		P: 6, 8, 9
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	E	E	E		E	E	E		E		P: 6, 8, 9
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	E	E	E		E	E	E		E		P: 6, 8, 9
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)											
Musculo-skeletal Superficial (including Nerve Blocking)											
Other (Urological)	E	E	E		E	E	E		E		P: 6, 8, 9

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [6] 3D
- [8] VPan
- [9] XView



(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K091009

For Prescription Use Only

7340 - CA430

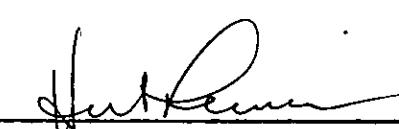
Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	E	E	E		E	E	E		E		P: 6, 8, 9
Abdominal	E	E	E		E	E	E		E	E	P: 6, 8, 9
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	E	E	E		E	E	E		E		P: 6, 8, 9
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)											
Musculo-skeletal Superficial (including Nerve Blocking)											
Other (Urological)	E	E	E		E	E	E		E		P: 6, 8, 9

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [6] 3D
- [8] VPan
- [9] XView


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K091009

For Prescription Use Only

7340 - CA431

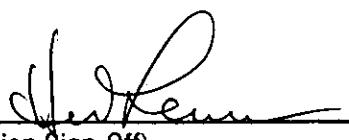
Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	E	E	E		E	E	E		E		P: 6, 8, 9
Abdominal	E	E	E		E	E	E		E		P: 6, 8, 9
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	E	E	E		E	E	E		E		P: 6, 8, 9
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	E	E	E		E	E	E		E		P: 6, 8, 9
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)	E	E	E		E	E	E		E		P: 6, 8, 9
Musculo-skeletal Superficial (including Nerve Blocking)	E	E	E		E	E	E		E		P: 6, 8, 9
Other (Urological)	E	E	E		E	E	E		E		P: 6, 8, 9

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [6] 3D
- [8] VPan
- [9] XView


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K091009

For Prescription Use Only

7340 - CA621

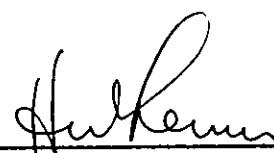
Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	E	E	E		E	E	E		E		P: 6, 8, 9
Abdominal	P	E	E		E	E	E		E		P: 6, 8, 9
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	E	E	E		E	E	E		E		P: 6, 8, 9
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	E	E	E		E	E	E		E		P: 6, 8, 9
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)											
Musculo-skeletal Superficial (including Nerve Blocking)											
Other (Urological)	E	E	E		E	E	E		E		P: 6, 8, 9

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [6] 3D
- [8] VPan
- [9] XView



(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K091009

For Prescription Use Only

7340 - CA631

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P		P		P: 5, 6, 8, 9, 10
Abdominal	P	P	P		P	P	P		P		P: 5, 6, 8, 9
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P		P: 5, 6, 8, 9
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P		P: 5, 6, 8, 9, 12
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9
Other (Urological)	P	P	P		P	P	P		P		P: 5, 6, 8, 9

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared: k081794)

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: B + M + PW + CFM + PD

[4] CMM

[5] MView

[6] 3D

[8] VPan

[9] XView

[10] QIMT

[12] Strain


(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K091009

For Prescription Use Only

7340 - 2 CW

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]				P							
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)											
Musculo-skeletal Superficial (including Nerve Blocking)											
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared: K081794)

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are:



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K091009

For Prescription Use Only

7340 - 5 CW

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular				P							
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)											
Musculo-skeletal Superficial (including Nerve Blocking)											
Other (Urological)											

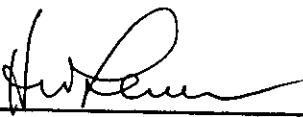
N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared: k081794)

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are:


(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K091009

For Prescription Use Only

7340 - E8-5

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal	E	E	E		E	E	E	E			P: 6, 8, 9
Transvaginal	E	E	E		E	E	E	E			P: 6, 8, 9
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)											
Musculo-skeletal Superficial (including Nerve Blocking)											
Other (Urological)	E	E	E		E	E	E	E			P: 6, 8, 9

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [6] 3D
- [8] VPan
- [9] XView



(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number K091009

For Prescription Use Only

7340 - EC123

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal	E	E	E		E	E	E		E		P: 6, 8, 9
Transvaginal	E	E	E		E	E	E		E		P: 6, 8, 9
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)											
Musculo-skeletal Superficial (including Nerve Blocking)											
Other (Urological)	E	E	E		E	E	E		E		P: 6, 8, 9

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [6] 3D
- [8] VPan
- [9] XView



(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number K09b09

For Prescription Use Only

7340 - EC1123

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P		P		5, 6, 8, 9, 10
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal	P	P	P		P	P	P		P		P: 5, 6, 8, 9; N: 14
Transvaginal	P	P	P		P	P	P		P		P: 5, 6, 8, 9
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)											
Musculo-skeletal Superficial (including Nerve Blocking)											
Other (Urological)	P	P	P		P	P	P		P		P: 5, 6, 8, 9

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E
(Previously cleared: k081794)

[1] Small Organs includes Breast, Thyroid and Testicles

121

Cardiac is Adult and Pediatric

[3]

Combined modes are: B + M +

[5]

SONN

[6]

3D

[8]

50

[8]

VI

[9]
116

View

[10]

QIMI

114

ElaXto

Heitman
(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K091009

7340 - TRT33

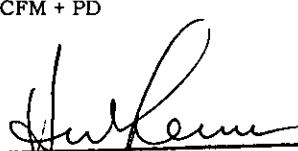
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal	P	P	P		P	P	P	P			P: 4, 5, 6, 8, 9, 13; N:14
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)											
Musculo-skeletal Superficial (including Nerve Blocking)											
Other (Urological)	P	P	P		P	P	P	P			P: 4, 5, 6, 8, 9, 13

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared: k081794)

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [4] CMM
- [5] MView
- [6] 3D
- [8] VPan
- [9] XView
- [13] TP View
- [14] ElaXto


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K091009

For Prescription Use Only

7340 - TEE022

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	CnTL	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P		P: 4, 6, 9, 11, 12
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)											
Musculo-skeletal Superficial (including Nerve Blocking)											
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared: k081794)

[1]

Small Organs includes Breast, Thyroid and Testicles

[2]

Cardiac is Adult and Pediatric

[3]

Combined modes are: B + M + PW + CW + CFM + PD

[4]

CMM

[6]

3D

[9]

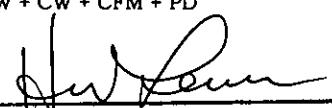
XView

[11]

Stress

[12]

Strain


(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K091009

For Prescription Use Only

7340 - TEE122

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P		P: 4, 6, 9, 11, 12
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)											
Musculo-skeletal Superficial (including Nerve Blocking)											
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared: k081794)

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: B + M + PW + CW + CFM + PD

[4] CMM

[6] 3D

[9] XView

[11] Stress

[12] Strain


(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number K091009

For Prescription Use Only

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9, 13
Intraoperative (Abdominal)	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9, 13
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9, 13
Small Organ [1]	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9, 13; N: 14
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9, 12, 13
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9, 13
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9, 13
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared: k081794)

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: B + M + PW + CFM + PD

[4] CMM

[5] MView

[6] 3D

[8] VPan

[9] XView

[12] Strain

[13] TP View

[14] ElaXto



(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number K091009

7340 - LP323

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9, 13
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic	P	P	P		P	P	P		P		P: 4, 5, 6, 8, 9, 13
Musculo-skeletal Conventional (including Nerve Blocking)											
Musculo-skeletal Superficial (including Nerve Blocking)											
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared: k081794)

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: B + M + PW + CFM + PD

[4] CMM

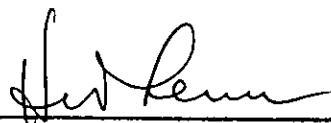
[5] MView

[6] 3D

[8] VPan

[9] XView

[13] TP View



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number 5091009

For Prescription Use Only

7340 - BC431

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P -		P	P	P		P		P: 5, 6, 7, 8, 9, 10
Abdominal	P	P	P		P	P	P		P		P: 5, 6, 7, 8, 9
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P		P: 5, 6, 7, 8, 9, 12
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)											
Musculo-skeletal Superficial (including Nerve Blocking)											
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared: k081794)

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: B + M + PW + CFM + PD

[5] MView

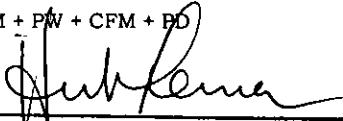
[6] 3D

[7] 4D

[8] VPan

[9] XView

[12] Strain


(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K091009

For Prescription Use Only

7340 - BE1123

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	N	N	N		N	N	N		N		5, 6, 7, 8, 9
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal	N	N	N		N	N	N		N		5, 6, 7, 8, 9
Transvaginal	N	N	N		N	N	N		N		5, 6, 7, 8, 9
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional (including Nerve Blocking)											
Musculo-skeletal Superficial (including Nerve Blocking)											
Other (Urological)	N	N	N		N	N	N		N		5, 6, 7, 8, 9

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

- [1] Small Organs includes Breast, Thyroid and Testicles
- [2] Cardiac is Adult and Pediatric
- [3] Combined modes are: B + M + PW + CFM + PD
- [5] MView
- [6] 3D
- [7] 4D
- [8] VPan
- [9] XView



(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number K091009

For Prescription Use Only

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P	P	P	P	P	P	P	P	P: 5, 6, 7, 8, 9, 12, 13
Abdominal	P	P	P	P	P	P	P	P	P	P	P: 5, 6, 7, 8, 9, 12, 13
Intraoperative (Abdominal)	P	P	P		P	P	P	P	P	P	P: 6, 8, 9, 12, 13
Intraoperative Neurological											
Pediatric	P	P	P	P	P	P	P	P	P	P	P: 5, 6, 7, 8, 9, 12, 13
Small Organ [1]	P	P	P	P	P	P	P	P	P	P	P: 5, 6, 7, 8, 9, 12, 13; N: 1
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	P: 5, 6, 8, 9, 12
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	P: 5, 6, 7, 9, 12
Cardiac [2]	P	P	P	P	P	P	P	P	P	P	P: 5, 6, 7, 8, 9, 10, 11, 12
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P	P	P: 5, 6, 9, 10, 11, 12
Transesophageal (Non Cardiac)											
Transrectal	P	P	P		P	P	P	P	P	P	P: 5, 6, 8, 9, 12, 13; N: 1
Transvaginal	P	P	P		P	P	P	P	P	P	P: 5, 6, 8, 9, 12, 13
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	P: 5, 6, 7, 8, 9, 12, 13, 14
Laparoscopic	P	P	P		P	P	P		P		P: 5, 6, 8, 9, 12, 13
Musculo-skeletal Conventional [3]	P	P	P	P	P	P	P	P	P	P	P: 5, 6, 7, 8, 9, 12, 13; N: 1
Musculo-skeletal Superficial [3]	P	P	P	P	P	P	P	P	P	P	P: 5, 6, 7, 8, 9, 12, 13; N: 1
Other (Urological)	P	P	P	P	P	P	P	P	P	P	P: 5, 6, 7, 8, 9, 12, 13

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared k051308, k052805, k060827, k081386)

[1] Small Organs includes

Breast, Thyroid and Testicles

[2] Cardiac is Adult and

Pediatric

[3] Musculo Skeletal - Nerve

Block-

[4] Combined modes are:

B+M+PW+CW+CFM+PD

[5] CMM

[6] 3D

[7] 4D

[8] VPan

[9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging (MView)

[13] TP-View

[14] IMT

[15] QIMT

[16] ElaXto

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number K091009

For Prescription Use Only

6150 - PA230

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P	P	P	P	P		P	E	P: 5, 6, 9
Abdominal	P	P	P	P	P	P	P	E	P	E	P: 5, 6, 9
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P	P	P	P	P		P	E	P: 5, 6, 9
Small Organ [1]	P	P	P	P	P	P	P		P	E	P: 5, 6, 9
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	E	P	E	P: 5, 6, 9
Cardiac [2]	P	P	P	P	P	P	P	E	P	E	P: 5, 6, 9, 10, 11
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P	P	P	P	P	E	P	E	P: 5, 6, 9
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared k051308)

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[4] Combined modes are:

B+M+PW+CW+CFM+PD

[5] CMM

[6] 3D

[9] XView

[10] Stress

[11] Xstrain


(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K091009

For Prescription Use Only

6150 - PA240

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CW D	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	E	E	E	E	E	E	E		E		P: 5, 6, 9
Abdominal	E	E	E	E	E	E	E		E		P: 5, 6, 9
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	E	E	E	E	E	E	E		E		P: 5, 6, 9
Small Organ [1]	E	E	E	E	E	E	E		E		P: 5, 6, 9
Neonatal Cephalic											
Adult Cephalic	E	E	E	E	E	E	E		E		P: 5, 6, 9
Cardiac [2]	E	E	E	E	E	E	E	E	E		P: 5, 6, 9, 10, 11
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	E	E	E	E	E	E	E		E		P: 5, 6, 9
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[4] Combined modes are:

B+M+PW+CW+CFM+PD

[5] CMM

[6] 3D

[9] XView

[10] Stress

[11] Xstrain


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K091009

6150 - PA121

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>											
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)	
Ophthalmic												
Fetal												
Abdominal	P	P	P	P	P	P	P	E	P	E	P: 5, 6, 9	
Intraoperative (Abdominal)												
Intraoperative Neurological												
Pediatric												
Small Organ [1]												
Neonatal Cephalic												
Adult Cephalic												
Cardiac [2]	P	P	P	P	P	P	P	E	P	E	P: 5, 6, 9, 10, 11	
Transesophageal (Cardiac)												
Transesophageal (Non Cardiac)												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Conventional [3]												
Musculo-skeletal Superficial [3]												
Other (Urological)												

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared k051308)

[2] Cardiac is Adult and Pediatric

[4] Combined modes are:

B+M+PW+CW+CFM+PD

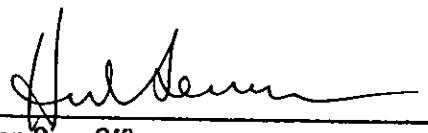
[5] CMM

[6] 3D

[9] XView

[10] Stress

[11] Xstrain



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number KC91C09

For Prescription Use Only

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal	E	E	E	E	E	E	E		E		P: 5, 6, 9
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P	P	P	P	P		E		P: 5, 6, 9
Small Organ [1]											
Neonatal Cephalic	P	P	P	P	P	P	P		E		P: 5, 6, 9
Adult Cephalic											
Cardiac [2]	P	P	P	P	P	P	P	E	E		P: 5, 6, 9, 10, 11
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P	P	P	P	P		E		P: 5, 6, 9
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared k051308)

[2] Cardiac is Adult and Pediatric

[4] Combined modes are:

B+M+PWD+CWD+CFM+PD

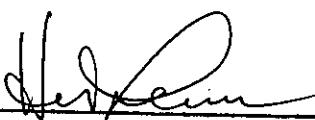
[5] CMM

[6] 3D

[9] XView

[10] Stress

[11] Xstrain



(Division Sign-Off)
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K091009

6150 - PA023

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CW D	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P	P	P	P	P		E		P: 5, 6, 9
Small Organ [1]											
Neonatal Cephalic	P	P	P	P	P	P	P		E		P: 5, 6, 9
Adult Cephalic											
Cardiac [2]	P	P	P	P	P	P	P		E		P: 5, 6, 9, 10, 11
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P	P	P	P	P		E		P: 5, 6, 9
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared k051308)

[2] Cardiac is Adult and

Pediatric

[4] Combined modes are:

B+M+PW+CW+CFM+PD

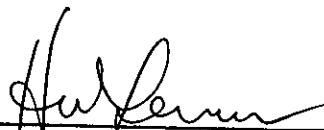
[5] CMM

[6] 3D

[9] XView

[10] Stress

[11] Xstrain



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K091009

For Prescription Use Only

6150 - LA332

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Abdominal	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Small Organ [1]	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13; N: 16
Neonatal Cephalic	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13, 15
Laparoscopic											
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13; N: 16
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13; N: 16
Other (Urological)	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

B+M+PW+CFM+PD

[6] 3D

[8] VPan

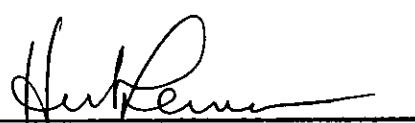
[9] XView

[12] Compound Imaging (MView)

[13] TP-View

[15] QIMT

[16] ElaXto



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number KC91009

For Prescription Use Only

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Abdominal	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		E		P: 6, 8, 9, 12, 13
Small Organ [1]	P	P	P		P	P	P		E		P: 6, 8, 9, 12, 13; N: 16
Neonatal Cephalic	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		E		P: 6, 8, 9, 12, 13, 14, 15
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		E		P: 6, 8, 9, 12, 13; N: 16
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		E		P: 6, 8, 9, 12, 13; N: 16
Other (Urological)	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared k051308)

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

B+M+PWD+CFM+PD

[6] 3D

[8] VPan

[9] XView

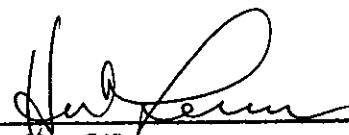
[12] Compound Imaging (MView)

[13] TP-View

[14] IMT

[15] QIMT

[16] ElaXto



(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number 15091009

6150 - LA523

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Abdominal	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P	E	P	E	P: 6, 8, 9, 12, 13
Small Organ [1]	P	P	P		P	P	P	E	P	E	P: 6, 8, 9, 12, 13; N:
Neonatal Cephalic	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P	E	P	E	P: 6, 8, 9, 12, 13, 14,
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P	E	P	E	P: 6, 8, 9, 12, 13; N:
Musculo-skeletal Superficial [3]	P	P	P		P	P	P	E	P	E	P: 6, 8, 9, 12, 13; N:
Other (Urological)	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared k051308)

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

B+M+PWD+CFM+PD

[6] 3D

[8] VPan

[9] XView

[12] Compound Imaging (MView)

[13] TP-View

[14] IMT

[15] QIMT

[16] ElaXto



(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K091009

For Prescription Use Only

6150 - LA532

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	E	E	E		E	E	E		E	E	P: 6, 8, 9, 12, 13
Abdominal	E	E	E		E	E	E		E	E	P: 6, 8, 9, 12, 13
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P	E	P	E	P: 6, 8, 9, 12, 13
Small Organ [1]	P	P	P		P	P	P	E	P	E	P: 6, 8, 9, 12, 13
Neonatal Cephalic	E	E	E		E	E	E		P	E	P: 6, 8, 9, 12, 13
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P	E	P	E	P: 6, 8, 9, 12, 13
Laparoscopic											
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		E	E	P: 6, 8, 9, 12, 13
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E	E	P: 6, 8, 9, 12, 13
Other (Urological)	E	E	E		E	E	E		E	E	P: 6, 8, 9, 12, 13

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared k051308)

[1] Small Organs includes Breast, Thyroid and Testicles

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

B+M+PW+CFM+PD

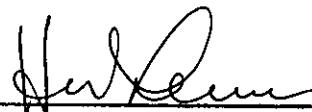
[6] 3D

[8] VPan

[9] XView

[12] Compound Imaging (MView)

[13] TP-View



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number 15091009

6150 - LA424

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		E		P: 6, 8, 9, 12, 13
Small Organ [1]	P	P	P		P	P	P		E		P: 6, 8, 9, 12, 13
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		E		P: 6, 8, 9, 12, 13
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		E		P: 6, 8, 9, 12, 13
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		E		P: 6, 8, 9, 12, 13
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared k051308)

[1] Small Organs includes Breast, Thyroid and Testicles

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

B+M+PW+CFM+PD

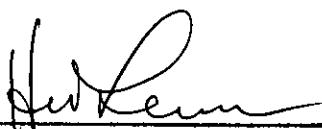
[6] 3D

[8] VPan

[9] XView

[12] Compound Imaging (MView)

[13] TP-View



(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number KC91009

For Prescription Use Only

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Abdominal	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Small Organ [1]	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13; N: 16
Neonatal Cephalic	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Laparoscopic											
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13; N: 16
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13; N: 16
Other (Urological)	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

B+M+PW+CFM+PD

[6] 3D

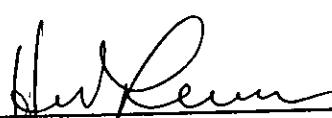
[8] VPan

[9] XView

[12] Compound Imaging (MView)

[13] TP-View

[16] ElaXto


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K091009

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Abdominal	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Small Organ [1]	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Neonatal Cephalic	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Laparoscopic											
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Other (Urological)	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

B+M+PWD+CFM+PD

[6] 3D

[8] VPan

[9] XView

[12] Compound Imaging (MView)

[13] TP-View



(Division Sign-Off)
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K091009

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mappin g (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12
Abdominal	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12
Small Organ [1]	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 10, 11, 12
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12
Laparoscopic											
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12
Other (Urological)	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

B+M+PW+CFM+PD

[5] CMM

[6] 3D

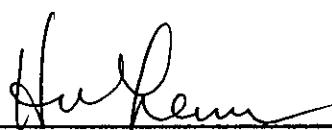
[8] VPan

[9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging



(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K091009

6150 - CA123

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>											
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)	
Ophthalmic												
Fetal	E	E	E		E	E	E		P		P: 5, 6, 8, 9, 12	
Abdominal	P	P	P		P	P	P	E	P	E	P: 5, 6, 8, 9, 12	
Intraoperative (Abdominal)												
Intraoperative Neurological												
Pediatric	P	P	P		P	P	P	E	P	E	P: 5, 6, 8, 9, 12	
Small Organ [1]	P	P	P		P	P	P	E	P	E	P: 5, 6, 8, 9, 12	
Neonatal Cephalic	P	P	P		P	P	P	E	P	E	P: 5, 6, 8, 9, 12	
Adult Cephalic											P: 5, 6, 8, 9, 12	
Cardiac [2]	P	P	P		P	P	P	E	P	E	P: 5, 6, 8, 9, 10, 11, 12	
Transesophageal (Cardiac)												
Transesophageal (Non Cardiac)												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular	P	P	P		P	P	P	E	P	E	P: 5, 6, 8, 9, 12	
Laparoscopic												
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		P		P: 5, 6, 8, 9, 12	
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		P		P: 5, 6, 8, 9, 12	
Other (Urological)												

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared k051308)

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block-

[4] Combined modes are:

B+M+PW+CFM+PD

[5] CMM

[6] 3D

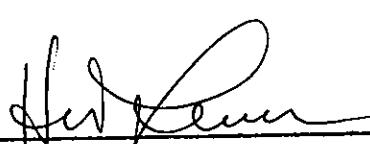
[8] VPan

[9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging (MView)


 (Division Sign-Off)
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K091009

6150 - CA421**Intended use:**

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P	E	P	E	P: 5, 6, 8, 9, 12
Abdominal	P	P	P		P	P	P	E	P	E	P: 5, 6, 8, 9, 12
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P	E	P	E	P: 5, 6, 8, 9, 12
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P	E	P	E	P: 5, 6, 8, 9, 12
Laparoscopic											
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12
Other (Urological)	P	P	P		P	P	P	E	P	E	P: 5, 6, 8, 9, 12

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared k051308)

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

B+M+PWD+CFM+PD

[5] CMM

[6] 3D

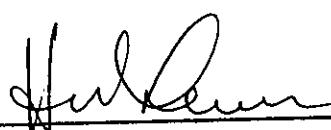
[8] VPan

[9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging (MView)


 (Division Sign-Off)
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K091009

For Prescription Use Only

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P	E	P	E	P: 5, 6, 8, 9, 12
Abdominal	P	P	P		P	P	P	E	P	E	P: 5, 6, 8, 9, 12
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	E	E	E		E	E	E		E		
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P	E	P	E	P: 5, 6, 8, 9, 12
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)	P	P	P		P	P	P	E	P	E	P: 5, 6, 8, 9, 12

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared k051308)

[4] Combined modes are:

B+M+PW+CFM+PD

[5] CMM

[6] 3D

[8] VPan

[9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging (MView)



(Division Sign-Off)
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K091009

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P		P	E	P: 5, 6, 8, 9, 12
Abdominal	P	P	P		P	P	P		P	E	P: 5, 6, 8, 9, 12
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	E	E	E		E	E	E		E	E	P: 5, 6, 8, 9, 12
Small Organ [1]	E	E	E		E	E	E		E	E	P: 5, 6, 8, 9, 12
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]	E	E	E		E	E	E		E	E	P: 5, 6, 8, 9, 10, 11, 12
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P	E	P: 5, 6, 8, 9, 12
Laparoscopic											
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		E	E	P: 5, 6, 8, 9, 12
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E	E	P: 5, 6, 8, 9, 12
Other (Urological)	E	E	E		E	E	E		E	E	P: 5, 6, 8, 9, 12

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared k051308)

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

B+M+PWD+CFM+PD

[5] CMM

[6] 3D

[8] VPan

[9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging (MView)



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices510(k) Number K091009

6150 - CA431

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	E	E	E		E	E	E		E	E	P: 5, 6, 8, 9, 12
Abdominal	E	E	E		E	E	E		E	E	P: 5, 6, 8, 9, 12
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	E	E	E		E	E	E		E	E	P: 5, 6, 8, 9, 12
Small Organ [1]	E	E	E		E	E	E		E	E	P: 5, 6, 8, 9, 12
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]	E	E	E		E	E	E		E	E	P: 5, 6, 8, 9, 10, 11, 12
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	E	E	E		E	E	E		E	E	P: 5, 6, 8, 9, 12
Laparoscopic											
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		E	E	P: 5, 6, 8, 9, 12
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E	E	P: 5, 6, 8, 9, 12
Other (Urological)	E	E	E		E	E	E		E	E	P: 5, 6, 8, 9, 12

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

B+M+PW+CFM+PD

[5] CMM

[6] 3D

[8] VPan

[9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging (MView)



(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K091009

For Prescription Use Only

6150 - CA631

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12
Abdominal	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12
Small Organ [1]	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 10, 11, 12
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12
Laparoscopic											
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12
Other (Urological)	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

B+M+PW+CFM+PD

[5] CMM

[6] 3D

[8] VPan

[9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging (MView)



(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number K091009

For Prescription Use Only

6150 - 2CW

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]					P						
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular					P						
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared k051308)

[2] Cardiac is Adult and Pediatric

[4] Combined modes are: CW



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K091009

For Prescription Use Only

61500 - 5CW

Intended use:

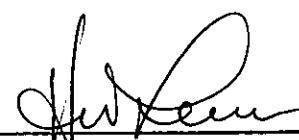
Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular				P							
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared k051308)

[4] Combined modes are: CW



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K091009

For Prescription Use Only

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P	E	P	E	P: 5, 6, 8, 9, 12
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal	P	P	P		P	P	P	E	P	E	P: 5, 6, 8, 9, 12
Transvaginal	P	P	P		P	P	P	E	P	E	P: 5, 6, 8, 9, 12
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)	P	P	P		P	P	P	E	P	E	P: 5, 6, 8, 9, 12

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared k051308)

[4] Combined modes are:

B+M+PW+CFM+PD

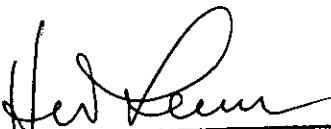
[5] CMM

[6] 3D

[8] VPan

[9] XView

[12] Compound Imaging (MView)



Ned Keen
 (Division Sign-Off)
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K091009

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12; N: 16
Transvaginal	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

[4] Combined modes are:

B+M+PW+CFM+PD

[5] CMM

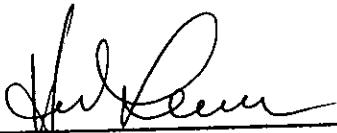
[6] 3D

[8] VPan

[9] XView

[12] Compound Imaging (MView)

[16] ElaXto



(Division Sign-Off)
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K091009

6150 - TEE022

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)	P	P	P	P	P	P	P	E	P		P: 5, 6, 9, 10, 11
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared k051308)

[4] Combined modes are:

B+M+PW+CW+CFM+PD

[5] CMM

[6] 3D

[9] XView

[10] Stress

[11] Xstrain


(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number 14091009

For Prescription Use Only

6150 - TEE132

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CW D	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)	E	E	E	E	E	E	E	E	E		P: 5, 6, 9, 10, 11
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

[4] Combined modes are:

B+M+PW+CW+CFM+PD

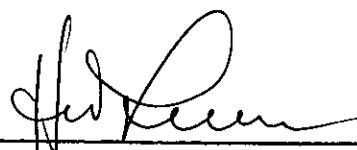
[5] CMM

[6] 3D

[9] XView

[10] Stress

[11] Xstrain



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number 5091009

For Prescription Use Only

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Abdominal	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Intraoperative (Abdominal)	P	P	P		P	P	P		P	P	P: 6, 8, 9, 12, 13
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P	P	P: 6, 8, 9, 12, 13
Small Organ [1]	P	P	P		P	P	P		P	P	P: 6, 8, 9, 12, 13; N: 16
Neonatal Cephalic	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P	P	P: 6, 8, 9, 12, 13
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P	P: 6, 8, 9, 12, 13
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P	P: 6, 8, 9, 12, 13
Other (Urological)	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared k052805)

[1] Small Organs includes Breast, Thyroid and Testicles

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

B+M+PW+CFM+PD

[6] 3D

[8] VPan

[9] XView

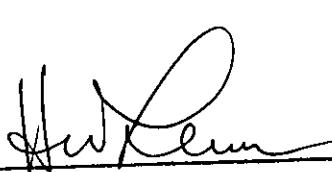
[12] Compound Imaging (MView)

[13] TP-View

[15] Automatic Gain

[17] FWI

[18] ElaXto



 (Division Sign-Off)
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K091009

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Abdominal	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Small Organ {1}	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Neonatal Cephalic											
Adult Cephalic											
Cardiac {2}											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Laparoscopic	E	E	E		E	E	E		E		P: 6, 8, 9, 12, 13
Musculo-skeletal Conventional {3}											
Musculo-skeletal Superficial {3}											
Other (Urological)											

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[4] Combined modes are:

B+M+PW+CFM+PD

[6] 3D

[8] VPan

[9] XView

[12] Compound Imaging (MView)

[13] TP-View



(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K091009

6150 - BC431

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping	Tissue Enhancement Imaging (TEI)	CnTl	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P	P	P	P	P: 5, 6, 7, 8, 9, 12
Abdominal	P	P	P		P	P	P	P	P	P	P: 5, 6, 7, 8, 9, 12
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P	P	P	P	P: 5, 6, 7, 8, 9, 12
Small Organ [1]	E	E	E		E	E	E		E		P: 5, 6, 7, 8, 9, 12
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]	E	E	E		E	E	E		E		P: 5, 6, 7, 8, 9, 10, 11, 12
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	P: 5, 6, 7, 8, 9, 12
Laparoscopic											
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		E		P: 5, 6, 7, 8, 9, 12
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E		P: 5, 6, 7, 8, 9, 12
Other (Urological)	P	P	P		P	P	P	P	P	P	P: 5, 6, 7, 8, 9, 12

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

(Previously cleared k060827)

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

B+M+PW+CFM+PD

[5] CMM

[6] 3D

[7] 4D

[8] VPan

[9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging (MView)



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K091009

For Prescription Use Only

6150 - BL433

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	E	E	E		E	E	E		E		P: 6, 7, 8, 9, 12, 13
Abdominal	E	E	E		E	E	E		E		P: 6, 7, 8, 9, 12, 13
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	E	E	E		E	E	E		E		P: 6, 7, 8, 9, 12, 13
Small Organ [1]	E	E	E		E	E	E		E		P: 6, 7, 8, 9, 12, 13
Neonatal Cephalic	E	E	E		E	E	E		E		P: 6, 7, 8, 9, 12, 13
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	E	E	E		E	E	E		E		P: 6, 7, 8, 9, 12, 13
Laparoscopic											
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		E		P: 6, 7, 8, 9, 12, 13
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E		P: 6, 7, 8, 9, 12, 13
Other (Urological)	E	E	E		E	E	E		E		P: 6, 7, 8, 9, 12, 13

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

[1] Small Organs includes Breast,
Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

B+M+PW+CFM+PD

[6] 3D

[7] 4D

[8] VPan

[9] XView

[12] Compound Imaging (MView)

[13] TP-View

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number 5091009

For Prescription Use Only

6150 - BE1123

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>										
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	N	N	N		N	N	N		N		5, 6, 8, 9,
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal	N	N	N		N	N	N		N		5, 6, 8, 9,
Transvaginal	N	N	N		N	N	N		N		5, 6, 8, 9,
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)	N	N	N		N	N	N		N		5, 6, 8, 9, 12

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

[4] Combined modes are:

B+M+PW+CFM+PD

[5] CMM

[6] 3D

[8] VPan

[9] XView

[12] Compound Imaging (MView)



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Division of Reproductive, Abdominal and
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510(k) Number 5091009

For Prescription Use Only

6150 - TRT33

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

<u>Clinical Application</u>	<u>Mode of Operations</u>											
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)	
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Abdominal)												
Intraoperative Neurological												
Pediatric												
Small Organ [1]												
Neonatal Cephalic												
Adult Cephalic												
Cardiac [2]												
Transesophageal (Cardiac)												
Transesophageal (Non Cardiac)												
Transrectal	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12, 13; N: 16	
Transvaginal	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12, 13; N: 16	
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Conventional [3]												
Musculo-skeletal Superficial [3]												
Other (Urological)	E	E	E		E	E	E		E		P: 5, 6, 8, 9, 12, 13	

N: New Indication, P: Previously cleared by FDA, E: Added under Appendix E

[4] Combined modes are:

B+M+PW+CFM+PD

[5] CMM

[6] 3D

[8] VPan

[9] XView

[12] Compound Imaging (MView)

[13] TP-View

[16] ElaXto

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Division of Reproductive, Abdominal and

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510(k) Number

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